



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,907	06/30/2000	RUDI WILFRIED JAN PAUWELS	07619.0006	4853

27777 7590 07/03/2003

AUDLEY A. CIAMPORCERO JR.
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

BAKER, MAURIE GARCIA

ART UNIT	PAPER NUMBER
----------	--------------

1639

DATE MAILED: 07/03/2003

221

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/530,907

Applicant(s)

Pauwels et al

Examiner

Maurie G. Baker, Ph.D.

Art Unit

1639



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 9, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 and 38-62 is/are pending in the application.
- 4a) Of the above, claim(s) 8, 11-16, 20-23, 38-40, and 42-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 10, 17-19, 24-36, and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

DETAILED ACTION

1. The Response filed April 9, 2003 (Paper No. 23) is acknowledged. Claims 1-36 and 38-62 are pending.

Election/Restriction

2. The last communication from the examiner was a Notice of Non-Responsive Amendment stating that the previous response filed on January 10, 2003 was deemed to be non-responsive with respect to election of species. Applicant's arguments filed April 9, 2003 in response to this Notice were found partially persuasive as applicant now elects as a species of solid support "film or tape" (Response, page 4). Thus, in the interest of compact prosecution, the case is now examined on the merits.

3. However, the following is noted for the record. There is still confusion as to the different species of solid support as applicant argues that they are not mutually exclusive. This confusion is reflected in the rejections under 35 USC 112, second paragraph below. The examiner has attempted to do her best in identifying which claims read on (all of the) elected species.

4. Applicant elected Group I for examination with traverse in Paper 15 and has provided further traversals in Papers 20 and 23. These traversals are addressed below.

5. First, with respect to the different Groups, Applicant argues that the PCT was not subjected to Lack of Unity requirements. This is immaterial to the instant case as the PCT case was acted upon by a different examiner. The instant examiner has made her own independent determination that the claims lack unity. The examiner set forth in the Restriction Requirement that there does not appear to be a technical feature that links all of the claims as there are two different methods and a device claimed (see paragraphs 10-13 of that action). Moreover, the method of Group I is known in the art as disclosed by Virtanen (US 6,342,349). This reference is described below. Thus the instant Groups I – III lack unity. For these reasons, restriction for examination purposes as indicated is proper and is made FINAL.

6. Therefore, claims 42-62 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

7. With respect to the species, applicant argues that they have not been set forth with particularity with “no indication of the criterion used to classify such species”. Criterion used to classify each species are not specifically required. The examiner stated that the species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. As stated in the action, the species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

PCT Rule 13.2 states that unity of invention shall be fulfilled when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features". It further defines "special technical feature" as "those technical features that define a contribution which each of the claimed inventions, claimed as a whole, makes over the prior art".

For example, unity of invention is fulfilled if:

- (a) all alternatives have a common property; and
- (b) (i) a common structure is present, i. e. a significant structural element is shared by all alternatives, or
- (b) (ii) in cases where the common structure can not be the unifying criterion, all alternatives belong to a recognized class of compounds in the art to which the invention pertains. (MPEP 1850).

In the instant case, part (a) above is not fulfilled because all claimed species do not have a common property (i.e. different physical and/or chemical characteristics). Further, all of the species do not belong to a recognized class in the art to which they pertain. Moreover, the claimed method is known in the art. For these reasons, election under these rules is proper and required.

8. Also, the examiner would like to note that the species were not set forth with the amount of particularity requested by applicant because the claims are unclear as to which read on the elected species. As stated above, the examiner has attempted to do her best in identifying which claims read on (all of the) elected species. Note that all of the previous species elections are in effect {(1) Species of solid support; (2) Species of analyte; (3) Species of semi-solid or liquid medium; (4) Species of target}.

9. Applicant has stated that claims 1-14, 17-19, 22-36 and 38 read directly or generically on the elected species of solid support: film or tape. Of these claims, claims 8, 11, 12-14, 22, 23 and 38-40 do not read on the elected species of medium (applicant has elected liquid and these claims read on semi-solid).

10. Therefore, claims 8, 11, 12-16, 20-22, 23 and 38-40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected species,

there being no allowable generic claim. Thus, claims 1-7, 9, 10, 17-19, 24-36 and 41 are currently under examination to the extent of the elected species.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1, 29, 30 and 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. Applicant's claims are directed to a method for the rapid screening of analytes. Claim 31 refers to a "so-called intelligent material". The disclosure simply does not adequately describe the "so-called intelligent material". Applicant's claimed scope represents only an invitation to experiment.

The language of the specification should describe the claimed invention so that one skilled in the art can recognize what is claimed. A description of a

compound in terms of its function fails to distinguish the compound from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *University of California v. Eli Lilly and Co.* (U.S. Court of Appeals Federal Circuit (CAFC) 43 USPQ2d 1398 7/22/1997 Decided July 22, 1997; No. 96-1175).

The disclosure is neither representative of the claimed genus, nor does it represent a substantial portion of the claimed genus. Moreover the claimed genus encompasses members which are yet to be prepared or envisioned. This further evidences that the specific examples set forth in the instant specification do not constitute support for the claimed genus or a substantial portion thereof.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1, 2, 4, 6, 17-19, 25-28³¹ and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are very confusing in general and the following applies to all claims: MPEP 2173.02: If the scope of the invention sought to be patented cannot be determined from the language of the claims with a reasonable degree of

certainty, a rejection of the claims under 35 U.S.C. 112, second paragraph is appropriate. *In re Wiggins*, 488 F.2d 538, 179 USPQ 421 (CCPA 1973).

This is especially true when one considers the election of species requirement in the instant case. The examiner asked repeatedly for clarification with respect to the instant claims and the elected species of solid support. Currently the elected species of solid support is film or tape. This is still deemed to be confusing with respect to certain dependent claims and how they read on the elected species. Rejections specific to each claim are set forth below.

A. With respect to the elected species of solid support is film or tape, claims 2, 4, 27, 28 and 41 are confusing because it is unclear how the "film or tape" can be placed in individually identifiable containers or different compartments.

B. Claim 6 is confusing because it is completely unclear how the material "allows for spontaneous release of the analytes". This is relative terminology which renders the claim indefinite. The terminology is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claim 7 is indefinite for the same reasons pertaining to "controlled release of the analytes".

C. Claims 17-19 are confusing because it is unclear how the elected support of "film or tape" is coated with a membrane, monolayer or film (claim 17) or is an information carrier (claim 18) or is reflective (claim 19).

D. With respect to the elected species of solid support is film or tape, claim 25 is confusing because it is unclear how each analyte can be applied to a single “film or tape” and claim 26 is confusing because it is unclear how the single “film or tape” can be rod or spherical shaped.

E. Claim 31 refers to a “so-called intelligent material”. This is completely indefinite as it is wholly unclear what is being referred to and thus the metes and bounds of the claim cannot be determined.

F. Claim 1 recites a method for the rapid screening of analytes. The term “rapid” is relative terminology which renders the claim indefinite. The terminology is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

16. Claims 1, 5-7, 17-19, 24-26, 29, 30, 32 and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Schwabacher et al (US 2002/0006604).

Schwabacher et al discloses a method of synthesizing and screening chemical compounds on a one-dimensional support (see Abstract and claims 32 and 34). This support can be a "tape" or an optical fiber, see paragraph 0027. The methods of Schwabacher et al read on the limitations of instant claims 5-7, 17-19, 24-26, 29, 30, 32 and 36 with respect to the method steps, analytes screened and detection methods. See paragraphs 0029, 0031, 0052-0071 and patented claims 32-37 of the reference.

Information Disclosure Statement

17. The Information Disclosure Statements are acknowledged; however, copies of the PTO-1449 forms are not in the file. The examiner is making efforts to locate these forms; however, resubmission of these documents, if possible, by applicant would facilitate their consideration and would be greatly appreciated by the examiner. A signed copy of the PTO-1449 will be mailed as soon as the examiner obtains copies of the references.

Status of Claims/Conclusion


18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is

(703) 308-0065. The examiner is on an increased flextime schedule but can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
June 26, 2003



MAURIE GARCIA BAKER PH.D.
PRIMARY EXAMINER